ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003034-86-04/F Helsinki, 5 June 2013

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Fatty acids, tall-oil, reaction products with triethanolamine, CAS No. 67784-78-5 (EC No. 267-053-1), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12 (1)(d) thereof for Fatty acids, tall-oil, reaction products with triethanolamine, CAS No. 67784-78-5 (EC No. 267-053-1), by [redacted] (Registrant), latest submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 18 January 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

- Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents (EU Method B.26/OECD Guideline 408) in rats, oral route.
- Prenatal Developmental Toxicity Study (EU Method B.31/OECD Guideline 414) in rats.
- Two-Generation Reproduction Toxicity Test (EU Method B.35/OECD Guideline 416) in rats, oral route.
- Fish, Juvenile Growth Test (OECD Guideline 215).
- Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei) (OECD Guideline 222).
- Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test (OECD Guideline 208).
- Soil Microorganisms: Nitrogen Transformation Test (OECD Guideline 216).

On 29 October 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 29 July 2011 until 12 September 2011. ECHA did receive information from third parties (see section III below).

On 16 July 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 16 August 2012 the Registrant did not provide any comments on the draft decision to ECHA. On 4 October 2012 the Registrant updated his registration dossier (justification for update provided by the Registrant: "change in the access granted to information"). There are no changes in the updated dossier related to testing proposals submitted initially by the Registrant.

On 18 January 2013 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 21 February 2013 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided not to amend the draft decision.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Articles 40(3)(a) and (b) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

- Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2, test method: EU B.26/OECD 408).
- Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2, test method: EU B.31/OECD 414).
- Long-term toxicity on terrestrial invertebrates (Annex IX, 9.4 column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222).
- Long-term toxicity testing on plants (Annex IX, 9.4 column 2; test method: Terrestrial plants, growth test, OECD 208, with at least six species tested (and as a minimum with two monocotyledonous

species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline));
- Effects on soil micro-organisms (Annex IX, 9.4.2; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216)

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

- Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1; test method: Fish, early-life stage toxicity test, OECD 210)

while the originally proposed Fish, Juvenile Growth Test according to test method OECD Guideline 215 (Annex IX, 9.1.6.3) proposed to be carried out using the registered substance is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

Pursuant to Article 40(3)(d) of the REACH Regulation the proposed two-generation reproductive toxicity study in rats, oral route, (Annex IX, 8.7.3) is currently rejected.

If the results of the sub-chronic toxicity study (90-day) required by this decision indicate adverse effects on reproductive organs or tissues then the Registrant shall submit a testing proposal to cover the endpoint of Annex IX, 8.7.3 for reproductive toxicity unless the Registrant considers that the specific rules for adaptation from this information requirement mentioned in Column 2, Annex IX, 8.7 apply.

In any event the Registrant may on the basis of other considerations submit a testing proposal for this end-point at an earlier stage. Such reasons for testing should be indicated.

The Registrant shall determine the appropriate order of the studies taking into account the possible outcomes and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **5 June 2015** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance and scientific information submitted by third parties.

1. Sub-chronic toxicity (90-day)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2 of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant proposed testing by the oral route. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate.

The Registrant specified that the species to be used for testing is rat. According to the test method EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the registered substance, Fatty acids, tall-oil, reaction products with triethanolamine.

2. Pre-natal developmental toxicity

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant specified that the species to be used for testing is rat. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. Furthermore, the Registrant did not specify the route to be used for testing. According to the test method EU B.31/OECD 414 the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414) using the registered substance, Fatty acids, tall-oil, reaction products with triethanolamine.

3. Two-generation reproductive toxicity

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

According to Section 8.7.3 of Annex IX of the REACH Regulation a two-generation reproductive toxicity study is required if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues. According to the technical dossier, the oral combined repeated dose toxicity study with the reproduction/developmental toxicity screening test showed no adverse effects on reproductive tissues or organs. Therefore, ECHA concludes that at this moment in time the Registrant is not legally required to cover in his registration the endpoint of Annex IX, 8.7.3 for reproductive toxicity.

Moreover, the Registrant did not indicate any specific reasons for performing the study immediately. In fact, the Registrant indicated in his tiered testing approach that this test should be postponed until the results of the sub-chronic toxicity study are available. On this basis the testing proposal is currently rejected. If the 90-day study shows adverse effects on reproductive organs or tissues, the Registrant shall submit a testing proposal to cover the endpoint of Annex IX, 8.7.3. as this would then constitute a standard information requirement for substances registered at 100 to 1000 tonnes per year.

In any event the Registrant may on the basis of other considerations submit a testing proposal for this end-point at an earlier stage. Such reasons for testing should be indicated.

b) Consideration of third party information

ECHA received third party information concerning the testing proposal during the public consultation.
The third party has requested ECHA to consider that all approvals for proposed two-generation reproductive toxicity tests be suspended and replaced by the extended one-generation reproductive toxicity study (EOGRTS). ECHA acknowledges that the OECD test guideline for an extended one generation reproductive toxicity study may be used as a valid option by the Registrant, if appropriate specifications to the study design are provided. Moreover, as indicated above ECHA has decided not to accept the current testing proposal for a two-generation reproductive toxicity test.

4. Long-term toxicity testing on fish

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may reject a testing proposal in accordance with Article 40(3)(d) but requiring the Registrant to carry out additional tests in case of non-compliance of the testing proposal with Annexes IX, X and XI of the REACH Regulation.

According to column 1, Section 9.1.6 of Annex IX of the REACH Regulation, long-term toxicity testing on fish is required to fulfil the standard information requirements. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant has submitted a testing proposal for a fish, juvenile growth test (OECD 215 guideline) to cover this standard information requirement.

The proposed OECD 215 guideline does not appear to be the appropriate test to be performed in order to fulfil the requirements of this endpoint for the registered substance. ECHA notes that according to the Guidance on information requirements and chemical safety assessment R.7.8.5.3 (p. 51) (ECHA, 2008) normally OECD 210 test would be considered appropriate for examining fish toxicity. However, OECD 215 test may also be considered for substances with log Kow (partition coefficient octanol-water) <5. In the registration dossier the Registrant concluded that the log Kow of the registered substance is >6. Furthermore, in the Chemical Safety Report the Registrant indicated that log Kow values for the representative structures of the test substance calculated using the well known and validated QSAR EPISuite 4.0 (US-EPA, 2000 - 2008) are between 5.6 and 23.1. Therefore, a test such as OECD 210 would be more suitable for this type of substance.

Accordingly pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following study: Fish, Early-Life Stage Toxicity Test (test method: OECD 210) using the registered substance, Fatty acids, tall-oil, reaction products with triethanolamine. The originally proposed test OECD Guideline 215 is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

5. Long-term toxicity testing on terrestrial invertebrates

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Short-term toxicity testing on terrestrial invertebrates is a standard information requirement as laid down in Annex IX, section 9.4.1 column 1 of the REACH Regulation. Annex IX, section 9.4., column 2 requires the Registrant to consider long-term toxicity testing instead of short-term in particular for substances that have a high potential to adsorb to soil or that are very persistent.

In proposing the test it is apparent that the Registrant considered that there is a need to perform long-term toxicity testing on terrestrial invertebrates. Accordingly, ECHA has assessed this registration dossier with the understanding that the Registrant has adapted the standard information requirement of Annex IX, section 9.4.1 in accordance with the rules set out in column 2 of Annex IX, section 9.4. With respect to the testing proposed ECHA has come to the conclusions set out below.

In the registration dossier the Registrant concluded that the estimated log Koc (organic carbon-water partition coefficient) of the major components of the registered substance is >5.6 at pH 4. Furthermore, the Registrant noted in the Chemical Safety Report that the substance contains ionisable components.

Therefore, because of the high adsorption potential of the substance, long-term toxicity testing to terrestrial organisms is necessary. The originally proposed OECD 222 test is capable to generate information that would allow in a reliable way to conclude on the long-term toxicity of a substance to terrestrial invertebrates. These considerations are also reflected in the Guidance on information requirements and chemical safety assessment R.7.11 (ECHA, 2008).

ECHA is not in a position to decide on the most appropriate test protocol, since that depends on species sensitivity and substance properties.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei) (test method: OECD 222) using the registered substance, Fatty acids, tall-oil, reaction products with triethanolamine.

6. Effects on soil micro-organisms

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Testing of effects on soil micro-organisms is a standard information requirement as laid down in Annex IX, section 9.4.2 of the REACH Regulation.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Soil Microorganisms: Nitrogen

Transformation Test (test method: EU C.21/OECD 216) using the registered substance, Fatty acids, tall-oil, reaction products with triethanolamine.

7. Toxicity testing on terrestrial plants

Pursuant to Article 40(3)(b) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test under modified conditions.

Short-term toxicity testing on terrestrial plants is a standard information requirement as laid down in Annex IX, section 9.4.3 column 1 of the REACH Regulation. Annex IX, section 9.4., column 2 requires the Registrant to consider long-term toxicity testing instead of short-term in particular for substances that have a high potential to adsorb to soil or that are very persistent

In proposing the test it is apparent that the Registrant considered that there is a need to perform a long-term toxicity testing on terrestrial plants. Accordingly, ECHA has assessed this registration dossier with the understanding that the Registrant has adapted the standard information requirement of Annex IX, section 9.4.3 in accordance with the rules set out in column 2 of Annex IX, section 9.4. With respect to the testing proposed ECHA has come to the conclusions set out below.

According to the Guidance on information requirements and chemical safety assessment R.7.11 (ECHA, 2008) the proposed OECD 208 test is designed to assess potential effects of substances on seedling emergence and growth. As such it does not cover chronic effects or effects on reproduction, however it is assumed to cover a sensitive stage in the life-cycle of a plant and therefore data obtained from this study have been used as estimates of chronic toxicity.

The OECD test guideline 208 reflects on the need to choose the number of species to be tested depending on relevant regulatory requirements and on the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing (Annex IX, 9.4, column 2) ECHA considers six species as the minimum to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The registrant should consider if testing on additional species is needed to cover the information requirement.

Accordingly, pursuant to Article 40(3)(b) of the REACH Regulation, the Registrant is required to carry out the proposed study: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, OECD 208, with at least six species (and as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline) tested using the registered substance, Fatty acids, tall-oil, reaction products with triethanolamine.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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It is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Finally, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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